

## REMARKS

Upon entry of this paper, claims 1 and 6 have been amended, claims 5 and 10 have been canceled, and no claims have been added as new claims. Thus claims 1-4 and 6-9 are presently pending in this application. No new matter has been added. The cancellation of claims 5 and 10 should in no way be construed to be an acquiescence to any of the rejections stated. Claims 5 and 10 are being canceled solely to expedite the prosecution of the present application. Applicant reserves the option to further prosecute the same or similar claims in the instant or a subsequent patent application.

### Summary of Invention in Pending Application

Prior to discussing the substantive rejections below, applicants wish to provide a brief summary of some of the features relating to what they regard as their invention as claimed in the pending application. This Summary is not intended to convey all of the inventive aspects of the present invention. Instead, this Summary is intended to merely point out some of the features that have been identified as relevant to the rejections stated in the Office Action.

The present claimed invention provides a covered stent that predictably and dependably expands to an increased diameter state at relatively low deployment pressures of less than about 10 atmospheres, while concomitantly minimizing the risk of tearing of the stent covering during expansion. The stent covering is comprised of an inner cover and an outer cover that are positioned adjacent the inner surface and outer surface, respectively, of the stent structure to cover the stent. The inner cover and the outer cover can be constructed from the same or different biocompatible materials, such as, fluoropolymers like expanded polytetrafluoroethylene, having a structure of nodes interconnected by fibrils.

The inventors have determined that decreasing the radial thickness of the covering and increasing the average internodal distance (IND) of the fluoropolymer material forming the stent covering, reduces the deployment pressure necessary to expand the covered stent to less than about 10 atmospheres.

In accordance with one aspect of the present invention, the stent covering has a radial thickness of at least about 0.008" when the stent is in the reduced diameter, unexpanded state. In accordance with another aspect of the present invention, the average internodal distance of the fluoropolymer material forming either the inner cover or the outer cover is greater than 100 microns when the stent is in the reduced diameter, unexpanded state.

In one embodiment, the average IND of the fluoropolymer material forming either the inner cover or the outer cover can be at least about 110 microns. Alternatively, the average IND of the fluoropolymer material forming either the inner cover or the outer cover can be at least about 135 microns.

#### **Discussion of Prior Claim Rejections under 35 U.S.C. §103**

##### *Claims 1-4*

Claims 1-4 were previously rejected under 35 U.S.C. §103 as allegedly being obvious over US Patent No. 6,124,523 to Banas (Banas '523) in view of US Patent No. 6,296,661 to Davila (Davila '661). Claim 1 has been amended to more clearly identify the present invention. Applicant further distinguishes the claimed invention from Banas '523 and Davila '661 according to the following remarks.

*Banas '523 and Davila '661 Fall Short Of Teaching Or Suggesting All Elements of Amended Claim 1*

As stated in the recent Office Action, Banas '523 does not disclose the expanded PTFE having an IND of more than 100 microns. The most recent Office Action further asserts that Davila '661 discloses a stent-graft implant comprising stent 60 sandwiched in graft material 70 of IND greater than 100 microns to allow a migration of cells to facilitate a more stable neointima on the surface of the stent-graft implant.

However, amended claim 1 further includes the characteristic of a deployment pressure requirement for expanding the stent of "less than 10 atmospheres." Neither Banas '523, nor Davila '661 teach or suggest an average deployment pressure of less than 10 atmospheres. This is further confirmed in the most recent Office Action in paragraph 2, where it states, "... BANAS and DAVILA disclose substantially all limitations as recited in the claims except for an average deployment pressure is less than 10 atm."

Applicants respectfully submit that amended claim 1 is therefore in condition for allowance. Claims 2-4 are likewise in condition for allowance as being dependent upon an allowable base claim, and also for their own claimed characteristics. Reconsideration and withdrawal of the rejection is respectfully requested.

*Claim 5*

Claim 5 was previously rejected under 35 U.S.C. §103 as being unpatentable over Banas '523 in view of Davila '661 and in further view of US Patent No. 6,039,755 to Edwin (Edwin '755). Claim 5 has been canceled in this Amendment and the subject matter incorporated into Claim 1 (upon which claim 5 previously depended). Therefore, Applicant further distinguishes the claimed invention from Banas '523, Davila '661, and Edwin '755 according to the following remarks.

*The Combination of Edwin '755 With Banas '523 and Davila '661 is Improper Because Edwin '755 Teaches Away From Such Combination And Edwin '755 Would Not Function With The Properties Of The Proposed Combination*

Edwin '755 was asserted for its alleged teaching of an ePTFE graft material suitable for use as a cover or liner for a stent-graft implant, which ePTFE is expanded under a pressure of less than 6 atm, and most preferably between 2-3 atm. To achieve expansion with a pressure of less than 6 atm, Edwin '755 discloses a comprehensive list of seven different parameters that must be met to obtain such an expansion characteristic.

Edwin '755 states repeatedly that "[c]onservation of the structural integrity of the ePTFE material is determined by conservation of the ePTFE microstructure structural integrity" See column 3, lines 32-34, *et al.* Edwin '755 goes on to repeatedly state seven (7) different properties required to maintain structural integrity, including the statement that, "[s]tructural integrity is considered retained where . . . IND remains substantially the same as the unexpanded graft . . ." See column 21, lines 34-48, *et al.* Further, Edwin '755 states that, "average outer surface internodal distance [i.e., IND] of the base graft is  $33\mu$ , at 3x is  $33\mu$ , at 4x is  $32\mu$  and at 5x is  $33\mu$ , . . ." See column 11, lines 45-47.

Edwin '755 also repeatedly discloses a large quantity of different measurements characterizing the ePTFE graft that will expand with under 6 atm of pressure. It further urges that there is a delicate balance between each of the characteristics, and the resulting structural integrity of the graft. The delicate balance is evidenced by four different instances of listing seven different criteria with ranges identified for maintaining structural integrity and still achieving an expansion pressure of less than 6 atm (1. Internodal distance, 2. Water entry pressure, 3. Wall thickness, 4. Average post-radial expansion, 5. Longitudinal tensile strength, 6. Radial tensile strength, and 7. Free of gross tears or fractures) See columns 3, 4, 9, and 21.

Edwin '755 also has a number of different examples, all of which teach an ePTFE substance that maintains an IND of between  $15\mu$  and  $33\mu$  to achieve an expansion pressure of less than 6 atm.

To interrupt the complicated combination of properties and characteristics by introducing an ePTFE graft with an internodal distance (IND) of greater than  $100\mu$  (100 microns) would result in an inoperable ePTFE graft under the teachings of Edwin '755. There is no mention whatsoever in Edwin '755 that the IND of the ePTFE can be altered at all beyond the range disclosed (between 15 and  $33\mu$ ). An IND of more than three times the disclosed IND in Edwin '755 would result in an ePTFE graft with insufficient structural integrity, which would tear easily.

The present claimed invention has surprisingly derived a different combination of characteristics or properties to form ". . . a stent covering . . . wherein at least one of said biocompatible material of said inner cover and said biocompatible material of said outer cover has a predetermined thickness and has an average internodal distance (IND) of greater than 100 microns to reduce a deployment pressure necessary to expand the stent to less than 10 atmospheres." *See* amended claim 1.

Banas '523, Davila '661, and Edwin '755, either individually or in combination, fail to teach a stent covering that is able to achieve the properties and characteristics of the claimed stent covering, without structural failure. As such, Applicants respectfully submit that claim 1 is allowable. Reconsideration and withdrawal of the rejection is respectfully requested.

#### *Claims 6-9*

Claims 6-9 were previously rejected under 35 U.S.C. §103 as allegedly being obvious over US Patent No. 6,124,523 to Banas (Banas '523) in view of US Patent No. 6,296,661 to Davila (Davila '661), and in further view of US patent No. 5,993,489 to Lewis (Lewis '489). Claim 6 has been amended to more clearly identify the present

invention. Applicant further distinguishes the claimed invention from Banas '523, Davila '661, and Lewis '489 according to the following remarks.

*Banas '523 and Davila '661 Fall Short Of Teaching Or Suggesting All Elements of Amended Claim 6, And The Addition Of Lewis '489 Does Not Remedy The Deficiency*

As discussed previously, as stated in the most recent Office Action, Banas '523 does not disclose the expanded PTFE having an IND of more than 100 microns. The most recent Office Action further asserts that Davila '661 discloses a stent-graft implant comprising stent 60 sandwiched in graft material 70 of IND greater than 100 microns to allow a migration of cells to facilitate a more stable neointima on the surface of the stent-graft implant.

However, amended claim 6 further includes the characteristic of a deployment pressure requirement for expanding the stent of "less than 10 atmospheres." Neither Banas '523, nor Davila '661 teach or suggest an average deployment pressure of less than 10 atmospheres. This is further confirmed in the Office Action in paragraph 2, where it states, "... BANAS and DAVILA disclose substantially all limitations as recited in the claims except for an average deployment pressure is less than 10 atm."

Lewis '489 has been asserted for allegedly introducing the feature of a cover thickness of at least about 0.008 inches. Therefore, Lewis '489 does not address the above deficiency in the combination of Banas '523 and Davila '661. As such, reconsideration and withdrawal of the rejection is respectfully requested.

*Claim 10*

Claim 10 was previously rejected under 35 U.S.C. §103 as being unpatentable over Banas '523 in view of Davila '661 and in further view of Lewis '489, and in further view of Edwin '755. Claim 10 has been canceled in this Amendment and the subject

matter incorporated into Claim 6 (upon which claim 10 previously depended). Therefore, Applicant further distinguishes the claimed invention from Banas '523, Davila '661, Edwin '755, and Lewis '489 according to the following remarks.

*The Combination of Edwin '755 With Banas '523, Davila '661, and Lewis '489 is Improper Because Edwin '755 Teaches Away From Such Combination And Edwin '755 Would Not Function With The Properties Of The Proposed Combination*

As discussed herein above, Banas '523, Davila '661, and Lewis '755 fail to teach or suggest all elements of the claimed invention of claims 6-9. For the reasons as stated in the above discussion of claim 5, the combination of Edwin '755 with Banas '523 and Davila '661 is improper. The further inclusion of Lewis '489 does not rectify this impropriety.

Edwin '755 was asserted for its alleged teaching of an ePTFE graft material suitable for use as a cover or liner for a stent-graft implant, which ePTFE is expanded under a pressure of less than 6 atm, and most preferably between 2-3 atm. To achieve expansion with a pressure of less than 6 atm, Edwin '755 discloses a comprehensive list of seven different parameters that must be met to obtain such an expansion characteristic.

To interrupt the complicated combination of properties and characteristics by introducing an ePTFE graft with an internodal distance (IND) of greater than 100 $\mu$  (100 microns) would result in an inoperable ePTFE graft under the teachings of Edwin '755. There is no mention whatsoever in Edwin '755 that the IND of the ePTFE can be altered at all beyond the range disclosed (between 15 and 33 $\mu$ ). An IND of more than three times the disclosed IND in Edwin '755 would result in an ePTFE graft with insufficient structural integrity, which would tear easily.

The present claimed invention has surprisingly derived a different combination of characteristics or properties to form a "... a stent covering ... wherein said stent

covering has a radial thickness of at least about 0.008" and the average internodal distance (IND) of each of the inner cover and the outer cover of greater than 100 microns to reduce a deployment pressure necessary to expand the stent to less than 10 atmospheres." *See* amended claim 6.

Banas '523, Davila '661, Lewis '489, and Edwin '755, either individually or in combination, fail to teach a stent covering that is able to achieve the properties and characteristics of the claimed stent covering, without structural failure. As such, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants respectfully submit that amended claim 6 is therefore in condition for allowance. Claims 7-9 are likewise in condition for allowance as being dependent upon an allowable base claim, and also for their own claimed characteristics.



### CONCLUSION

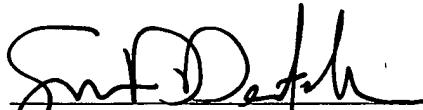
In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicant courteously solicits allowance of the claims in the form of a Notice of Allowance. Should there be any further outstanding issues of patentability following the entry of this amendment, a telephone interview is respectfully requested to resolve such issues.

Attached hereto is a marked-up version of any changes made to the Specification and/or Claims by the current Amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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IN THE CLAIMS

Claims 5 and 10 have been canceled without prejudice or disclaimer of the subject matter therein.

Claims 1 and 6 are requested to be amended as follows:

1. (Twice Amended) A radially deployable stent comprising:
  - a stent structure having an inner surface and an outer surface, and
  - a stent covering comprising
    - an inner cover of biocompatible material positioned adjacent said inner surface of said stent structure, and
    - an outer cover of biocompatible material positioned adjacent said outer surface of said stent structure,
  - wherein at least one of said biocompatible material of said inner cover and said biocompatible material of said outer cover has a predetermined thickness and has an average internodal distance (IND) of greater than 100 microns to reduce a deployment pressure necessary to expand the stent to less than 10 atmospheres.
  
6. (Twice Amended) A radially deployable stent comprising:
  - a stent structure having an inner surface and an outer surface, and
  - a stent covering comprising
    - an inner cover of biocompatible material positioned adjacent said inner surface of said stent structure, and
    - an outer cover of biocompatible material positioned adjacent said outer surface of said stent structure,
  - wherein said stent covering has a radial thickness of at least about 0.008" and the average internodal distance (IND) of each of the inner cover and the outer cover of greater than 100 microns to reduce a deployment pressure necessary to expand the stent to less than 10 atmospheres.